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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/399,003 09/20/99 HOGREFE

H 04121.0116-0

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HM22/1001

EXAMINER

TAYLOR, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1655

DATE MAILED:

10/01/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|-------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/399,003 | HOGREFE ET AL. |
| | Examiner | Art Unit |
| | Janell Taylor Cleveland | 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 July 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 58-68 and 75-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 58-68 and 75-95 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 58 and 84, drawn to a nucleic acid.

Group II, claim(s) 59-61, 64-68, 77-80, and 85, drawn to a P45 protein.

Group III, claim(s) 62-63, drawn to an antibody.

Group IV, claim(s) 75-76, drawn to a method of detecting PEF activity.

Group V, claim(s) 81-83, drawn to a method of producing P45.

Group VI, claim(s) 86, drawn to a method for cloning a PEF activity.

Group VII, claim(s) 87-93, drawn to PCR enhancing protein extract.

Group VIII, claim(s) 94-95, drawn to a computer readable medium and a computer based screening method.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I and II are unrelated. In the instant case the different inventions are drawn to a nucleic acid and a protein, which have different functions, i.e., the nucleic acid codes for protein and the protein is used for various purposes in the cell, in the instant case as

a polymerase enhancer. The nucleic acid is capable of functioning to code for a peptide without the peptide being present, and can be used by the practitioner to create probes, primers, and for diagnostic purposes without the presence of the peptide. Furthermore, the peptide is capable of functioning without the nucleic acid being present in the cell, as well as being useful to the practitioner by functioning to as a polymerase enhancer.

Groups I, II and III are unrelated. In the instant case the different inventions are drawn to nucleic acids and proteins; and antibodies. Antibodies have different functions than proteins and nucleic acids, i.e., the antibody attaches to the protein, often disabling it from functioning, and the protein is useful for carrying out various cellular functions.

The protein and the nucleic acid are capable of functioning in the cell without the antibody being present, and can be used by the practitioner to create enzymes, or for diagnostic testing, or in the case of nucleic acids, to form probes or primers.

Furthermore, the peptide is capable of functioning without the antibody being present in the cell, in fact, the protein usually cannot function when the antibody is present.

Inventions I-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and to a method. The method of detecting PEF activity has a different effect than the PEF protein itself, as there may be PEF present which is not functioning. Furthermore, the method does not require that PEF protein, nucleic acids, or antibodies be present.

Inventions II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case P45 may be found naturally, and therefore can be made by a materially different process. Also, the process may be used to make other products, by using a different protein.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product may be practiced with any materially different product, i.e. any protein which has PEF activity.

Inventions I-VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are comprised of different products, namely

PEF and PCR enhancing protein extract. These do not have the same function or the same effect.

Inventions I-VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a computer readable medium and other methods and products. These inventions have different modes of operation, as the computer uses electricity and generates data, while the other claims are related to a biological product.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products with different modes of operation, and are not related to one another.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland whose telephone number is 703-305-0273. The examiner can normally be reached on M-F 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janell Taylor Cleveland
Examiner
Art Unit 1655

September 25, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

9/27/01